

MUSCULOSKELETAL TUMOR SOCIETY

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December 20, 1999

Document Management Branch (HFA - 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket Number 97N-484S

To Whom It May Concern:

This is a letter regarding the proposed FDA regulations that appeared in the September 30, 1999, issue of the Federal Registry. It seems apparent that the FDA is anxious to regulate some types of allografts as medical devices. It must be understood that these allograft articles are already in clinical practice and have been used in various forms for many years. Any interference by the government in the regulation of these products is not only an intrusion on the already-established practice and use of these grafts, but it is an intrusion between the doctor-patient relationship. It also has a tremendous impact on grafts that are already in place in thousands of patients across the United States.

As the medical director of a tissue procurement agency and the medical director of a processing facility, as well as the president of the Musculoskeletal Tumor Society, I must vigorously oppose this proposal stated in the Federal Registry. If you would like to discuss this further or establish some sort of forum, please let me know. I would be glad to assist in the facilitation of the discussion regarding this subject.

Dr. Antonio Pereira and I have had several discussions regarding these matters. If you would like to discuss them further, please have him contact me.

Sincerely,

Ross M. Wilkins, M.D.

President, Musculoskeletal Tumor Society

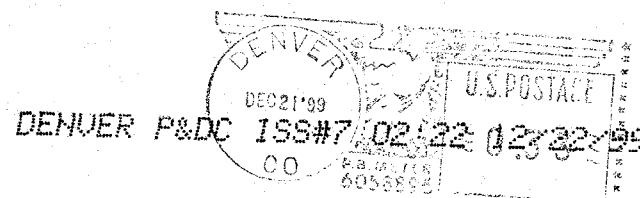
RMW/sab

97N 484S

2000 SPECIALTY DAY MEETING- SATURDAY, MARCH 18TH, ORLANDO, FL
2000 ANNUAL MEETING - MAY 11-13TH, GAINESVILLE, FL

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